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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,051	01/30/2004	Joshua D. Rabinowitz	00042.04CON	7033

7590 03/08/2005

IP Department  
Alexza Molecular Delivery Corporation  
1001 East Meadow Circle  
Palo Alto, CA 94303

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/769,051

Applicant(s)

RABINOWITZ ET AL.

Examiner

Mina Haghighatian

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-66 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 09/24/04.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,814,955 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 1-66 are generic to all that is recited in claims of U.S. Patent No. 6,814,955 B2. That is, claims of U.S. Patent No. 6,814,955 B2 fall entirely within the scope of claims 1-66, or in other words, claims 1-66 are anticipated by claims of U.S. Patent No. 6,814,955 B2. Specifically, the compositions and method of producing an active compounds such as chlordiazepoxide, testosterone, betahistine, estrogen esters, estradiol esters, etc, recited in instant claims 1-66 are anticipated by the composition for delivery and method of producing them as recited in claims 1-5 of U.S. Patent No. 6,814,955 B2. The rate of particle formation as recited in claims of the instant application are disclosed in the specification of U.S. Patent No. 6,814,955 B2.

Claims 1-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-28 of copending Application No. 10/769,046. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 1-66 are generic to all that is recited in claims of copending Application No. 10/769,046. That is, claims of copending Application No. 10/769,046 fall entirely within the scope of claims 1-66, or in other words, claims 1-66 are anticipated by claims of copending Application No. 10/769,046. Specifically, the compositions and method of producing an active compounds such as chlordiazepoxide, testosterone, betahistine, estrogen esters, estradiol esters, etc, recited in instant claims 1-66 are ~~anticipated by the method of administering an active compounds and the kit comprising the~~ composition and a device of copending Application No. 10/769,046.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of copending Application No. 10/718,982. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 1-66 are generic to all that is recited in claims of copending Application No. 10/718,982. That is, claims of copending Application No. 10/718,982 fall entirely within the scope of claims 1-66, or in other words,

claims 1-66 are anticipated by claims of copending Application No. 10/718,982. Specifically, the compositions and method of producing an active compounds such as chlordiazepoxide, testosterone, betahistine, estrogens, estrogen esters, estradiol esters, etc, recited in instant claims 1-66 are anticipated by the compositions and the kit comprising the compositions and a device of copending Application No. 10/718,982.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 16, 22, 28, 49, 55, 61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 9-11 of U.S. Patent No. 6,737,042 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 16, 22, 28, 49, 55, 61 are generic to all that is recited in claims of U.S. Patent No. 6,737,042 B2. That is, claims of U.S. Patent No. 6,737,042 B2 fall entirely within the scope of claims 16, 22, 28, 49, 55, 61, or in other words, claims 16, 22, 28, 49, 55, 61 are anticipated by claims of U.S. Patent No. 6,737,042 B2. Specifically, the compositions and method of producing an active compounds such as chlordiazepoxide, testosterone, betahistine, estrogen esters, estradiol esters, etc, recited in instant claims 16, 22, 28, 49, 55, 61 are anticipated by the composition for delivery and method of producing them as recited in claims 1-2 and 9-11 of U.S. Patent No. 6,737,042 B2. The rate of particle formation as recited in claims of the instant application are disclosed in the specification of U.S. Patent No. 6,737,042 B2.

Claims 16, 22, 28, 49, 55, 61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/768,205 and 10/749,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 16, 22, 28, 49, 55, 61 are generic to all that is recited in claims of copending Application Nos. 10/768,205 and 10/749,783. That is, claims of copending Application Nos. 10/768,205 and 10/749,783 fall entirely within the scope of claims 16, 22, 28, 49, 55, 61, or in other words, claims 16, 22, 28, 49, 55, 61 are anticipated by claims of copending Application Nos. 10/768,205 and 10/749,783. Specifically, the compositions, method of producing and method of treating a disease comprising ~~an active compounds such as estrogen esters, estradiol esters, ethinyl estradiol esters, etc,~~ recited in instant claims 16, 22, 28, 49, 55, 61 are anticipated by the compositions and method of administering the active compounds and the kit comprising the composition and a device of copending Application Nos. 10/768,205 and 10/749,783.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian

March 02, 2005



MICHAEL HARTLEY  
PRIMARY EXAMINER